



Medicenna Reports Fiscal Year 2022 Financial Results and Operational Highlights

June 22, 2022

--Cash runway extended late into calendar Q2 2023

--Tumor control achieved following MDNA11 treatment in 3 out of 8 patients enrolled in first 3 dose escalation cohorts of the ABILITY Phase 1/2 Study.

-- Pharmacodynamic data show superior dose-dependent increase in stimulation of anti-cancer immune cells when compared to competing IL-2 programs in the clinic

-- Management hosting conference call and webcast today at 8:30 AM ET

TORONTO and HOUSTON, June 22, 2022 (GLOBE NEWSWIRE) -- Medicenna Therapeutics Corp. ("Medicenna" or "the Company") (NASDAQ: MDNA TSX: MDNA), a clinical stage immunotherapy company, today announced its financial results and operational highlights for the fiscal year ended March 31, 2022. All dollar amounts are expressed in Canadian currency unless otherwise noted.

"Over the past fiscal year, we made significant progress highlighted by initial clinical data in low dose cohorts where 3 of 8 patients showed tumor control including 2 patients with rare but aggressive forms of metastatic sarcomas," said Dr. Fahar Merchant, President and CEO of Medicenna. "Dose-dependent and multi-fold increases in the population of cancer fighting immune cells have been observed in the first 3 dose cohorts where these increases have been substantially elevated when compared to competing IL-2 variants in the clinic at equivalent doses. We look forward to sharing additional monotherapy data from MDNA11's ABILITY study throughout 2022."

Dr. Merchant continued, "We have also demonstrated the versatility and deep pipeline potential of our Superkine and BiSKITs platform, established world class scientific, development and clinical advisory boards, completed a comprehensive commercial package for MDNA55 as we continue to diligently pursue out-licensing efforts while maintaining a solid cash balance at the end of this fiscal year."

Based on Medicenna's current development plans it is anticipated that the current cash on hand will be sufficient to fund operations late into the second calendar quarter of 2023.

Program highlights for the year ended March 31, 2022, along with recent developments include:

MDNA11: IL-2 Superkine Program

Throughout fiscal year 2022, Medicenna completed activities associated with GMP compliant manufacturing of MDNA11 the Company's selective, long-acting and novel IL-2 super-agonist. for the Phase 1/2 ABILITY Study, IND enabling studies required for regulatory submissions to commence first in human clinical trials with MDNA11 and secured clearance of the various applications submitted to regulatory agencies in Australia, US and Canada. The study is enrolling patients at clinical sites in the United States, Canada, and Australia, and is currently progressing through its fourth dose escalation cohort.

Although it is too early to draw meaningful conclusions on efficacy potential of MDNA11 from the dose escalation portion of the clinical trial, encouraging signs of selective CD8 T and NK cell activation and proliferation in the periphery have been observed in most patients treated in the first 3 cohorts achieving tumor control in 3 out of the 8 patients. MDNA11 has exhibited an acceptable safety profile in the ABILITY study, with no dose limiting toxicities reported to date, predicted pharmacokinetic characteristics with no apparent signs of immunogenicity.

Following observations from the first few cohorts in the study as well as learnings from competitor data and recent failures, Medicenna is utilizing a step-up dosing strategy from Cohort 4 onwards. This strategy entails first treating patients with two "priming doses" to habituate them to MDNA11 before stepping up to the higher fixed dose that is being evaluated. This is expected to increase chances of identifying MDNA11's optimum dose and is in line with the FDA's recently released "Project Optimus" initiative, which encourages companies to find the optimal dose and schedule for oncology drugs. While the step-up dosing (SUD) regimen is designed to further improve patient outcomes, the observation period for dose-limiting toxicities (DLTs) increases from 4 weeks to 8 weeks. Accordingly, clinical data from dose Cohort 4 will be available in Q3 of calendar 2022 with a full set of efficacy data for all dose escalation cohorts in Q4 of calendar 2022.

IL-4/IL-13 Super-Antagonists and Bifunctional SuperKine ImmunoTherapies (BiSKITs™) Program

In April 2022 Medicenna presented results from two of its novel preclinical assets at American Association for Cancer Research meeting. One poster focused on Fc-MDNA413, which is derived from Medicenna's Superkine platform and consists of a long-acting IL-13 super-antagonist for targeting immunologically cold tumors and a second poster featured a preclinical candidate from our BiSKITs program consisting of an anti-PD-1 antibody linked to an IL-2 super-agonist thereby achieving dual synergistic activities within a single molecule. These novel Superkine designs address unmet needs and have the potential for replacing block-buster checkpoint inhibitors which go off-patent after 2028.

MDNA55: Recurrent Glioblastoma (rGBM) Program

Throughout fiscal year 2022, Medicenna's MDNA55 program was highlighted in both peer-reviewed publications and at medical conferences. In May 2021, Medicenna announced a [peer-reviewed publication](#) in *Clinical Cancer Research* and in the third quarter of fiscal 2022, the design of a planned open-label hybrid Phase 3 trial of MDNA55 in rGBM was highlighted in a [peer-reviewed manuscript](#) published in *The Lancet Oncology*, and in an oral presentation at the Society for Neuro-Oncology and American Society of Clinical Oncology's First Annual Conference on CNS Clinical Trials. Additionally, John H. Sampson, M.D., Ph.D., MHSc, MBA, Robert H. and Gloria Wilkins Distinguished Professor of Neurosurgery at Duke University School of Medicine and member of Medicenna's Board of Directors, received The Abstract Award for Excellence in Clinical Trials in connection with an

oral presentation on MDNA55 at the 26th Annual Meeting of the Society for Neuro-Oncology. Medicenna continues to seek a strategic partnership to facilitate MDNA55's further development and commercialization and remains in active discussions in pursuit of this goal.

Operational Highlights

Throughout fiscal year 2022, Medicenna formally established crucial relationships with experts and key opinion leaders throughout industry and academia to gain important insights on the development of its pipeline.

In March 2022, the Company announced the appointment of Dr. Kapil Dhingra as a Strategic Advisor. Dr. Dhingra is a highly accomplished physician-scientist with experience guiding multiple drugs to approval. Simultaneously, Medicenna announced the formation of a Clinical Advisory Board (CAB) comprised of leading experts in immunotherapy and drug development. Members of the CAB include Drs. Paolo Ascierto, Lillian Siu and Hussein Tawbi.

In January 2022, Medicenna announced the formation of its Scientific Advisory Board (SAB). Members of the SAB are well recognized leaders in the fields of cancer immunotherapy and drug development and include Drs. Sergio Quezada, (Chairman), Burkhard Becher, David Mooney, and William Redmond.

In January 2022, Medicenna announced the appointments of industry veterans Dr. Peter Lloyd, Dr. L. Bruce Pearce, and Paul Smith to the Company's Development Advisory Committee and the appointment of Dr. Martin Bexon as interim Chief Medical Officer.

In September 2021, Medicenna announced the appointment of Dr. John Sampson to its Board of Directors.

Expected Upcoming Milestones

Initial PK/PD data from the fourth dose escalation cohort of the Phase 1/2 ABILITY study expected in July 2022.

Identification of MDNA11's recommended Phase 2 dose (RP2D) in the ABILITY study expected in the fourth quarter of calendar 2022.

Commencement of the ABILITY study's single agent expansion phase expected in the fourth quarter of calendar 2022.

Clinical update from the ABILITY study expected in the fourth quarter of calendar 2022.

Annual Financial Results

Medicenna had cash, cash equivalents, and marketable securities of \$20.5 million at March 31, 2022. These funds provide the Company with sufficient capital to execute its current planned expenditures late into the second quarter of calendar 2023 and important upcoming catalysts based on its current plans and projections.

Net loss for the year ended March 31, 2022, was \$22.6 million, or \$0.42 per share, compared to a loss of \$17.3 million, or \$0.35 per share for the year ended March 31, 2021. The increase in net loss for the year ended March 31, 2022, compared with the year ended March 31, 2021, was primarily a result of increased expenditures related to the MDNA11 development program as well as higher general and administrative expenses associated with the Company's Nasdaq listing in August 2020.

Research and development expenses of \$14.7 million were incurred during the year ended March 31, 2022, compared with \$10.9 million incurred in the year March 31, 2021. The increase in research and development expenses in the current year is primarily attributable to costs associated with the development of MDNA11 including pre-clinical studies, manufacturing of GMP materials for the clinical trial and clinical and regulatory costs associated with initiation of the Phase 1/2 ABILITY study.

General and administrative expenses of \$7.8 million were incurred during the year ended March 31, 2022, compared with \$6.5 million during the year ended March 31, 2021. The increase in expenditures year over year is primarily attributed to a full year of costs associated with Medicenna's Nasdaq listing and corresponding D&O insurance compared with only nine months of expenses in the prior year period.

Conference Call and Webcast

Medicenna will host a conference call and webcast today at 8:30 AM ET. To access the call, please dial 1-877-407-9716 from the United States or 1-201-493-6779 internationally, and refer to conference ID: 13729367. To access the live webcast, visit this [link to the event](#). Following the live webcast, an archived version of the call will be available on Medicenna's website.

About Medicenna

Medicenna is a clinical stage immunotherapy company focused on the development of novel, highly selective versions of IL-2, IL-4 and IL-13 Superkines and first in class Empowered Superkines. Medicenna's long-acting IL-2 Superkine, MDNA11, is a next-generation IL-2 with superior CD122 (IL-2 receptor beta) binding without CD25 (IL-2 receptor alpha) affinity thereby preferentially stimulating cancer killing effector T cells and NK cells. Medicenna's early-stage BiSKITs™ program, (Bi)functional SuperKine ImmunoTherapies) is designed to enhance the ability of Superkines to treat immunologically "cold" tumors. Medicenna's IL-4 Empowered Superkine, MDNA55, has been studied in 5 clinical trials including a Phase 2b trial for recurrent GBM, the most common and uniformly fatal form of brain cancer. MDNA55 has obtained Fast-Track and Orphan Drug status from the FDA and FDA/EMA, respectively.

Forward-Looking Statements

This news release contains forward-looking statements under applicable securities laws. Forward-looking statements are often identified by terms such as "will", "may", "should", "anticipate", "expects", "believes", "seeks" and similar expressions. All statements other than statements of historical fact, included in this release, including statements related to cash runway, the clinical potential and development and safety profile of MDNA11 and the Superkine and BiSKITs platform, upcoming milestones and the sharing of additional data and out-licensing efforts for MDNA55 are forward-looking statements that are subject to risks and uncertainties. There can be no assurance that such statements will prove to be accurate and actual results and future events could differ materially from those anticipated in such statements. Important factors that could cause actual results to differ materially from the Company's expectations include the risks detailed in the annual information form and Form 20-F of the Company and in other filings made by the Company with the applicable securities regulators from time to time in Canada and the United States.

The reader is cautioned that assumptions used in the preparation of any forward-looking information may prove to be incorrect. Events or circumstances may cause actual results to differ materially from those predicted, as a result of numerous known and unknown risks, uncertainties, and other factors, many of which are beyond the control of the Company. The reader is cautioned not to place undue reliance on any forward-looking information. Such information, although considered reasonable by management, may prove to be incorrect and actual results may differ materially from those anticipated. Forward-looking statements contained in this news release are expressly qualified by this cautionary statement. The forward-looking statements contained in this news release are made as of the date hereof and except as required by law, we do not intend and do not assume any obligation to update or revise publicly any of the included forward-looking statements.

Further Information:

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Source: Medicenna Therapeutics Corp.